

Attorney Docket: 920607-95550  
Amendment A

## **II. REMARKS**

### **A. Introduction**

Applicants submit this Response in a bona fide attempt to (i) advance the prosecution of this case, (ii) answer each and every ground of objection and rejection as set forth by the Examiner, (iii) place the claims in a condition for allowance, and (iv) place the case in better condition for consideration on appeal. Applicants respectfully request reexamination and reconsideration of the above referenced patent application in view of this Response.

As indicated above, Claims 1 - 12 have been amended. New Claims 13 - 15 have also been added.

Applicants respectfully submit that the noted amendments merely make explicit that which was (and is) disclosed or implicit in the original disclosure. The amendments thus add nothing that would not be reasonably apparent to a person of ordinary skill in the art to which the invention pertains.

### **B. Response to Objections**

The Examiner has rejected Claim 12 under 37 CFR 1.75(c) "as being of improper dependent form for failing to further limit the subject matter of a previous claim." Applicants have accordingly amended Claim 12 to change the dependency of Claim 12 from Claim 5 to Claim 6.

### **C. Response to Rejections**

#### **1. Double Patenting**

The Examiner has rejected Claims 1 - 12 under the judicially created doctrine of obviousness-type double patenting "as being unpatentable over claims 1 - 10 of U.S. Patent No. 6,681,136." The Examiner contends:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims meet the limitations of the applications claims except for delivering it to a blood pressure regulatory point. It would have been obvious to one having ordinary skill in the art at the time the invention was made to [modulate] blood pressure by activating the baroreceptors.

Attorney Docket: 920607-95550  
Amendment A

The Examiner has thus concluded that Applicants' invention, as recited in Claims 1-12, would have been obvious to one having ordinary skill in the art in view of the claims in the '136 patent and in light of Kieval et al.

In *In re Kaplan*, 789 F.2d 1574, 229 U.S.P.Q. 678 (Fed. Cir. 1986), the Federal Circuit stressed that to establish "obviousness-type" double patenting as to an attempt to obtain a patent on a variation of an invention claimed in a prior patent, there must be some *clear evidence* why the variation would have been obvious. As set forth below, Applicants respectfully submit that the record is devoid of the requisite clear evidence that the claimed invention would be obvious in view of the '136 patent, alone or in combination with Kieval et al.

Applicants initially submit that the instant invention is specifically directed to the transmission of waveform signals operative in the control of blood pressure to a blood pressure regulatory point. As is well known in the art, a blood pressure regulatory point can comprise the brain, more specifically, the hypothalamus, medulla or medullopontine region of the brainstem. The regulatory point can also comprise the vagus nerve, which carries signals for regulating blood pressure.

The Claims in the '136 patent are directed to the transmission of waveforms to a "target zone" in the body. The "target zone" discussed in the various embodiments and shown in the figures is however solely the zone 40 proximate "the carotid body and carotid sinus between the angle of the jaw 44 at the ear 42 down to the clavicular notch, which is where the clavicular bone 46 meets the sternum 48." Col. 7, ll. 18-22

Applicants accordingly submit that the transmission of selected waveform signals to a blood pressure regulatory point would *not* be obvious to one having ordinary skill in the art in view of the '136 patent.

The Examiner has further concluded that a blood pressure regulatory point must be a baroreceptor. Contrary to the Examiner's contention, Applicants respectfully submit that a blood pressure regulatory point need not be a baroreceptor. Indeed, as stated above, a blood pressure regulatory point could also be the brain, more specifically, the hypothalamus, medulla or medullopontine region of the brainstem, or the vagus nerve.

The noted distinction would *not* be obvious to one having ordinary skill in the art.

Attorney Docket: 920607-95550  
Amendment A

Applicants thus respectfully request that the double patenting rejection be withdrawn.<sup>1</sup>

## 2. 35 U.S.C. § 101

The Examiner has rejected Claims 6 and 12 under 35 U.S.C. § 101. The Examiner contends that “the claimed invention is directed to non-statutory subject matter.”

Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders [claims 6 and 12] non-statutory.

Applicants have accordingly amended Claim 6 to reflect that the treatment member “is adapted to be in communication with the body.” Claim 12 has also been amended to reflect that the treatment member “is adapted to be implanted in the body.”

## 3. 35 U.S.C. § 112

The Examiner has rejected Claims 7 – 11 under 35 U.S.C. § 112, second paragraph, “as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.”

Applicants have accordingly amended Claims 7 – 11 to change the dependency of the noted claims from Claim 5 to Claim 6, as recommended by the Examiner.

## 4. 35 U.S.C. § 102

The Examiner has rejected Claims 1-6 and 9-12 “under 35 U.S.C. § 102(e) as being anticipated by... Kieval et al (US 6,522,926).” The Examiner contends, *inter alia*:

Kieval et al. discloses a device for reducing blood pressure by activating baroreceptors. As seen in Figure 3, “the control system 60 generates a control signal as a function of the received sensor signal. The control signal activates, deactivates or otherwise modulates the baroreceptor activation device 70. Typically, activation of the device 70 results in activation of the baroreceptors 30” (col. 9, lines 33-37). The examiner considers the control system to be the storage area where the signals are generated.

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<sup>1</sup> Applicants further submit that, as asserted by the Examiner in the instant application, Claim 1 in the '136 patent could be deemed directed to non-statutory matter and, hence, found invalid, since the claim recites that the treatment member is in contact with the body.

Attorney Docket: 920607-95550  
Amendment A

In the alternative, Kieval et al. discloses the claimed invention except for the memory to store waveforms. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control system and method as taught by Kieval et al. with memory to store waveforms since it was known in the art that storing and recording data can provide physicians with information on the status of their patient.

The Examiner further contends that "Kieval et al. discloses a control system 60, with a memory 62 and a processor 63, which meet the definition of a computer."

It is well established that a rejection for anticipation under § 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference. *See In re Paulsen*, 30 F.3d 1475, 1478-79, 31 U.S.P.Q. 2d 1671, 1673 (Fed. Cir. 1994); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 U.S.P.Q. 2d 1001 (Fed. Cir.1991). *See also American Permahedge, Inc. v. Barcana, Inc.*, 857 F. Supp. 308, 32 U.S.P.Q. 2d 1801, 1807-08 (S.D. NY 1994) ("Prior art anticipates an invention ... if a single prior art reference contains each and every element of the patent at issue, operating in the same fashion to perform the identical function as the patent product. ... Thus, any degree of physical difference between the patented product and the prior art, *no matter how slight*, defeats the claim of anticipation."); *Transco Ex parte Levy*, 17 U.S.P.Q. 2d 1461, 1462 (Bd. Pat. App. & Int'l 1990) ("[I]t is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference".)

Applicants respectfully submit that the claimed invention is *not* anticipated by Kieval et al. Indeed, as discussed in detail below, Kieval et al. simply does not disclose "each and every limitation of the claimed invention."

Independent Claim 1, as amended, includes the steps of (i) providing a plurality of waveform signals representative of waveform signals generated in the body and carried by neurons in the body, the plurality of waveform signals including first waveform signals operative in the control of blood pressure and (ii) broadcasting the first waveform signals from a treatment member "directly" to a blood pressure regulatory point in the body.

The apparatus recited in independent Claim 6, as amended, includes (i) a source of collected waveform signals indicative of body organ functioning, the waveform signals including first waveform signals operative in the control of blood pressure and (ii) a treatment member

Attorney Docket: 920607-95550  
Amendment A

adapted to broadcast the first waveform signals "directly" to a blood pressure regulatory point in the body.

Applicants' waveform signals thus specifically include waveform signals that are similar to the waveforms or waveform signals that are naturally produced by the brain stem structures for modulating blood pressure. The type, form and function of the waveform signals transmitted to the blood pressure regulatory point are thus *solely* determined or dictated by the actual waveform signals generated in the body to modulate blood pressure.

Further, the waveform signals are broadcasted or transmitted "directly" to a blood pressure regulatory point by the treatment member. The noted communication by and between the treatment member and blood pressure regulatory point is thus achieved without an intermediate component or device.

In contrast, Kieval et al. discloses generating and transmitting "user determined" and "device determinative" control signals, which are *not* related to or representative of waveform signals generated in the body, to an intermediate component, i.e., a baroreceptor activation device, to effect a change in the baroreflex system.

Generally speaking, the baroreceptor activation device may be activated, deactivated or otherwise modulated to activate one or more baroreceptors and induce a baroreceptor signal or a change in the baroreceptor signal to thereby effect a change in the baroreflex system. The baroreceptor activation device may be activated, deactivated, or otherwise modulated continuously, periodically, or episodically. The baroreceptor activation device may comprise a wide variety of devices which utilize mechanical, electrical, thermal, chemical, biological, or other means to activate the baroreceptor. The baroreceptor may be activated directly, or activated indirectly via the adjacent vascular tissue. The baroreceptor activation device may be positioned inside the vascular lumen (i.e., intravascularly), outside the vascular wall (i.e., extravascularly) or within the vascular wall (i.e., intramurally). (emphasis added) Col. 3, ll. 40-55

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The control signals generated by the control system 60 may be continuous, periodic, episodic or a combination thereof, as dictated by an algorithm contained in memory. Continuous control signals include a constant pulse, a continuous train of pulses, a triggered pulse and a triggered train of pulses. Examples of periodic control signals described above which have a designated start time (e.g., beginning of each minute, hour or day) and a designated duration

Attorney Docket: 920607-95550  
Amendment A

(e.g., 1 second, 1 minute, 1 hour). Examples of episodic control signals include each of the continuous control signals described above which are triggered by an episode (e.g., activation by patient/physician, an increase in blood pressure above a certain threshold, etc. (emphasis added) Col. 9, ll. 52-65

Kieval et al. thus transmits "user determined and selected" and "device determinative" signals to a baroreceptor activation device. See, for example, Col. 10, ll. 58-63 (electrical signals to actuate a driver 66); Col. 11, ll. 41-61 (selective delivery of electrical power to a deformable structure device 140); Col. 14, ll. 11-35 (selective actuation of a magnetic coil 224 to create a magnetic field, which, in turn, moves magnetic particles); Col. 16, ll. 35-38 (electrical control signals to activate an electrode structure 282). The Kieval et al. signals are thus substantially different in type, form and function from Applicants' waveform signals.

Kieval et al thus does not disclose "each and every limitation of the claimed invention." Applicants accordingly respectfully request that the rejection under 35 U.S.C. § 102 be withdrawn.

#### 5. 35 U.S.C. § 103

The Examiner has alternatively rejected Claims 1-12 under 35 U.S.C. § 103(a) as being unpatentable over Kieval et al. The Examiner primarily contends that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control system and method as taught by Kieval et al. with a memory to store waveforms since it was known in the art that storing and recording data can provide physicians with information on the status of a patient."

It is well established that in determining what is and what is not obvious under § 103, all properties and advantages not in the prior art must be considered. See *In re Wright*, 848 F.2d 1216, 6 U.S.P.Q. 2d 1959, 1962 (Fed. Cir. 1988) ("Factors including unexpected results, new features, solution of a different problem, novel properties, are all considerations in the determination of obviousness in terms of 35 U.S.C. § 103"). Indeed, it is the invention as a whole, including distinct functions of the invention (including components or steps thereof), that must be considered in obviousness determinations.

It is further well established that a § 103 rejection based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in the reference,

Attorney Docket: 920607-95550  
Amendment A

is not proper and a prima facie case of obviousness cannot properly be asserted. In short, there would be "no technological motivation for engaging in the modification or change. To the contrary, there would be a disincentive. See *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).

Applicants respectfully submit that Claims 1-12 define an invention that is unobvious over Kieval et al. As set forth above, Applicants' apparatus and method employ "waveform signals representative of waveform signals generated in the body and carried by neurons in the body." The noted waveform signals are stored and selectively transmitted *directly* to a blood pressure regulatory point in the body, whereby the blood pressure is modulated.

Kieval et al. simply does not teach or suggest the direct transmission of waveform signals representative of waveform signals generated in the body and carried by neurons to modulate blood pressure. Kieval et al. merely teaches the use of "continuous control signals, periodic control signals, episodic control signals, or combinations thereof" that are specifically and solely tailored to activate a baroreceptor activation device, which, in turn, activates and/or controls baroreceptors. The control signals are thus "user determined", "device determinative" and *not* related to or representative of waveform signals generated in the body.

Applicants further submit that the asserted modification of Kieval et al.'s control system, i.e., storing and transmitting the waveform signals employed in Applicants' invention, would destroy the intent, purpose and function of the control system and baroreceptor activation device. Indeed, as set forth above, the signals employed in Kieval et al are "device determinative" and, hence, tailored to activate a selected baroreceptor activation device. The Kieval et al. system thus simply would not function if the waveform signals employed by Applicants were transmitted to the baroreceptor activation device.

Applicants thus submit the claimed invention should be deemed unobvious over Kieval et al. Applicants accordingly respectfully request that the § 103 rejection be withdrawn.

Applicants have also reviewed the prior art made of record and not relied upon by the Examiner and have found them not to teach or make obvious the present invention.

Attorney Docket: 920607-95550  
Amendment A

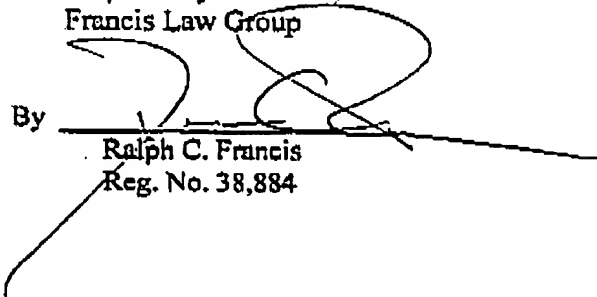
### III. CONCLUSION

Applicants having answered each and every ground of objection and rejection as set forth by the Examiner, and having added no new matter, believe that this response clearly overcomes the reference of record, and now submit that all claims in the above-referenced patent application are in condition for allowance and the same is respectfully solicited.

If the Examiner has any further questions or comments, Applicants invite the Examiner to contact their Attorneys of record at the telephone number below to expedite prosecution of the application.

Respectfully submitted,  
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